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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,439	01/05/2006	Stephen Robert Wedge	056291-5227	9937

9629 7590 09/10/2008  
MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER
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PACKARD, BENJAMIN J

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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09/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,439	<b>Applicant(s)</b> WEDGE, STEPHEN ROBERT	
	<b>Examiner</b> Benjamin Packard	<b>Art Unit</b> 1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06/06/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,4,7,8 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 4, 7, 8, and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed 06/06/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary

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**Claims 3, 7, 8, and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (Journal of Clinical Oncology, Vol 20, No 18, 2002: pp 3815-3825), in view of Galligioni et al (Lung Cancer 34 (2001) S3–S7) and Malik et al (Targets, Vol. 2, No. 2 April 2003 pp 48-57).

Herbst et al teaches administration of ZD1839 (Iressa) to patients with non-small cell lung cancer (page 3817 table 1 and page 3821 Antitumor Activity section). Herbst et al also teach it is known in the art that non-small-cell lung cancer is related to high expression of EGFR, which promotes tumor growth (page 3815 first and second paragraph).

Herbst et al does not disclose the treatment of non-small cell lung cancer with AZD2171.

Galligioni et al discloses treatment of non-small cell lung cancer with inhibitors of VEFT and VEGFR (see abstract and pg S5 which discusses the tyrosine-kinase VEGFR-2 receptor inhibitor SU 5416).

Galligioni et al does not disclose AZD2171 as a VEGFR inhibitor.

Malik teaches AZD2171 as a VEGFR-2 inhibiting agent (table 3 page 52 and page 54 middle of left column).

Malik does not teach the combined treatment with ZD1839 (Iressa) or the use of AZD2171 specifically for the treatment of non-small cell lung cancer

First, one of ordinary skill in the art would recognize the ability to substitute the VEGFR-2 inhibitor of Galligioni et al with the VEGFR-2 inhibitor of Malik, where both compounds inhibit the same expression, for the treatment of non-small cell lung cancer.

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As such, one of ordinary skill in the art would then be motivated to have combined the agents of the primary and the teaching of the two secondary references in order to provide a third chemotherapeutic composition useful for the same purpose (treating non-small cell lung cancer). This position is consistent with well-established precedent holding that it is prima facie obvious to combine compositions known to be individually useful together so as to provide a third composition for the same use. See, e.g., In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980).

It should be noted that claims 3, 4, and 15 do not require the combination, but may be administered sequentially separated by a period of time. Similarly, the preamble “pharmaceutical composition” and “kit” of claims 7 and 8 may be interpreted broadly to read on separate drugs in separate containers.

**Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (Journal of Clinical Oncology, Vol 20, No 18, 2002: pp 3815-3825), in view of Galligioni et al (Lung Cancer 34 (2001) S3–S7), Malik et al (Targets, Vol. 2, No. 2 April 2003 pp 48-57), and Weichselbaum et al (US 6,420,335, see 892 dated 12/10/2007).

Herbst et al, Galligioni et al, and Malik et al are discussed above. They do not teach the combination treatment with ionization.

Weichselbaum et al teaches combining treatment of cancers with combination anti-angiogenic compounds and ionizing radiation (claim 1). Of particular interest is non-small cell lung cancer (col 32 lines 45-48).

It would be obvious to one of ordinary skill in the art to substitute the anti-angiogenic compounds with other compounds known to treat the same cancer in the disclosed method of Weichselbaum et al, such as the combination discussed above.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612